

CLAIMS

1. A method of reducing restenosis comprising:

providing a drug delivery stent having a dosage of paclitaxel for delivery to
5 an artery, the dosage arranged such that substantially all the paclitaxel is releasable
from the stent upon implantation of the stent in the artery;

implanting the stent within an artery of a patient; and

delivering paclitaxel from the stent to the artery at a minimum release rate of
1 percent of the total dosage of paclitaxel on the stent per day throughout an entire
10 administration period from the time of implantation of the stent until the time that
substantially all the paclitaxel is released from the stent.

2. The method of Claim 1, wherein the administration period is about
20 to about 40 days from the date of implantation.

3. The method of Claim 1, wherein the release profile of the paclitaxel
after day one is substantially linear.

4. The method of Claim 1, wherein the amount of paclitaxel released
20 per day after day one is about 0.0003 to about 0.03 ug/mm² of tissue surface area.

5. The method of Claim 1, wherein the paclitaxel is deposited in
openings in the stent.

6. The method of Claim 1, wherein the paclitaxel is contained in a
25 bioresorbable matrix.

7. The method of Claim 1, wherein the paclitaxel is contained in a
polymer matrix.

8. The method of Claim 1, wherein the paclitaxel is delivered primarily
murally from the stent.

9. The method of Claim 1, wherein the step of delivering paclitaxel
5 further comprises delivering 2-25% of the total amount of paclitaxel loaded into the
stent in the first day, then delivering 95% of the loaded paclitaxel by day 20 to 45.

10. The method of Claim 1, wherein the step of delivering paclitaxel
further comprises delivering paclitaxel after day one at a rate of about 0.25
10 micrograms to about 2.5 microgram per day for a minimum of 21 days for a stent
with dimensions 3.0 mm in expanded diameter by 17 mm in length, and delivering
other amounts from stents of other dimensions based on their respective relative
proportions.

11. The method of Claim 1, wherein the step of delivering paclitaxel
15 further comprises delivering more than 80% of the paclitaxel loaded on the stent in
no longer than 180 days.

12. A method of reducing restenosis comprising:
20 providing a drug delivery stent having a dosage of paclitaxel for delivery to
an artery;
implanting the stent within an artery of a patient; and
delivering paclitaxel from the stent to the artery at a substantially linear
release rate over an entire period from day one after implantation through day
25 twenty five after implantation, wherein the amount of paclitaxel delivered during
the period is at least 25% of the drug loaded on the stent.

13. The method of Claim 12, wherein the amount of paclitaxel released
per day after day one is about 0.0003 to about 0.03 ug/mm² of tissue surface area.

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14. The method of Claim 12, wherein the paclitaxel is deposited in
openings in the stent.

15. The method of Claim 12, wherein the paclitaxel is contained in a bioresorbable polymer matrix.

5 16. The method of Claim 12, wherein the paclitaxel is delivered primarily murally from the stent.

17. The method of Claim 12, wherein the step of delivering paclitaxel further comprises delivering 2-25% of the total amount of paclitaxel loaded into the
10 stent in the first day, then delivering 95% of the loaded paclitaxel by day 20 to 45.

18. The method of Claim 12, wherein the step of delivering paclitaxel further comprises delivering more than 80% of the paclitaxel loaded on the stent in no longer than 30 days.

15 19. A method of reducing restenosis comprising:
providing a drug delivery stent having a dosage of paclitaxel for delivery to an artery;
implanting the stent within an artery of a patient; and
20 delivering paclitaxel from the stent to the artery, wherein at least 80% of the entire dosage of paclitaxel provided by the stent is delivered to the artery within 60 days of implantation.

20. The method of Claim 19, wherein the release profile of the paclitaxel
25 after day one is substantially linear.

22. The method of Claim 19, wherein the amount of paclitaxel released per day after day one is about 0.0003 to about 0.03 ug/mm² of tissue surface area.

30 23. The method of Claim 19, wherein the paclitaxel is deposited in openings in the stent.

24. The method of Claim 19, wherein the paclitaxel is contained in a bioresorbable polymer matrix.

25. The method of Claim 19, wherein the paclitaxel is delivered
5 primarily murally from the stent.

26. The method of Claim 1, wherein the step of delivering paclitaxel further comprises delivering paclitaxel after day one at a rate of about 0.25 micrograms to about 2.5 microgram per day for a minimum of 21 days for a stent
10 with dimensions 3.0 mm in expanded diameter by 17 mm in length, and delivering other amounts from stents of other dimensions based on their respective relative proportions.

27. A method of reducing restenosis comprising:
15 providing a drug delivery stent having a dosage of an anti-restenotic drug for delivery to an artery, the dosage arranged such that substantially all the drug is releasable from the stent upon implantation of the stent in the artery;
implanting the stent within an artery of a patient; and
delivering the drug from the stent to the artery at a minimum release rate of
20 1 percent of the total dosage of the drug on the stent per day throughout an entire administration period from the time of implantation of the stent until the time that substantially all the drug is released from the stent, wherein the release rate of the drug is substantially linear from at least day two through day 25.

28. The method of Claim 27, wherein the administration period is about
25 20 to about 40 days from the date of implantation.

29. The method of Claim 27, wherein the drug is deposited in openings
in the stent.

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30. The method of Claim 27, wherein the drug is contained in a bioresorbable polymer matrix.

31. The method of Claim 27, wherein the drug is delivered primarily
murally from the stent.

32. The method of Claim 27, wherein the step of delivering drug further
5 comprises delivering 2-25% of the total amount of drug loaded into the stent in the
first day, then delivering 95% of the loaded drug by day 20 to 45.

33. The method of Claim 1, wherein the step of delivering drug further
comprises delivering more than 80% of the drug loaded on the stent in no longer
10 than 180 days.

34. The method of Claim 1, wherein the step of delivering drug further
comprises releasing the drug at a substantially linear release rate in which r^2 is
greater than 0.95 after the first day of delivery and with less than 25% of the total
15 drug loaded delivered in the first day.

35. A method of treating a patient comprising:
providing a drug delivery stent having a dosage of therapeutic agent for
delivery to an artery, the dosage arranged such that substantially all the agent is
20 releasable from the stent upon implantation of the stent in the artery;
implanting the stent within an artery of a patient; and
delivering the agent from the stent to the artery at a minimum release rate of
1 percent of the total dosage of the agent on the stent per day throughout an entire
administration period from the time of implantation of the stent until the time that
25 substantially all the drug is released from the stent, wherein the release rate of the
drug after day one is substantially linear from at least day 2 through day 25.

36. The method of Claim 35, wherein the administration period is about
20 to about 40 days from the date of implantation.

37. The method of Claim 35, wherein the drug is deposited in openings
in the stent.

38. The method of Claim 35, wherein the drug is contained in a bioresorbable polymer matrix.

5 39. The method of Claim 35, wherein the step of delivering drug further comprises releasing the drug at a substantially linear release rate in which r^2 is greater than 0.95 after the first day of delivery and with less than 25% of the total drug loaded delivered in the first day.

10 40. A stent for reducing restenosis comprising:
a drug delivery stent having initial unexpanded diameter for insertion of the stent into a coronary artery and an expanded diameter for implantation within a coronary artery, the stent having a dosage of paclitaxel for delivery to an artery, the dosage arranged such that substantially all the paclitaxel is releasable from the stent
15 upon implantation of the stent in the artery, wherein the dosage of paclitaxel is arranged to be released at a minimum release rate of 1 percent of the total dosage of paclitaxel on the stent per day throughout an entire administration period from the time of implantation of the stent until the time that substantially all the paclitaxel is released from the stent.

20 41. The stent of Claim 40, wherein the administration period is about 20 to about 40 days from the date of implantation.

25 42. The stent of Claim 40, wherein the release rate of the paclitaxel after day one is substantially linear.

43. The stent of Claim 40, wherein the amount of paclitaxel released per day after day one is about 0.0003 to about 0.03 ug/mm² of tissue surface area.

30 44. The stent of Claim 40, wherein the paclitaxel is deposited in openings in the stent.

45. The stent of Claim 40, wherein the paclitaxel is contained in a bioresorbable matrix.

46. The stent of Claim 40, wherein the paclitaxel is contained in a
5 polymer matrix.

47. The stent of Claim 40, wherein the paclitaxel is arranged to be delivered primarily murally from the stent.

10 48. The stent of Claim 40, wherein the paclitaxel is affixed to the stent such that 2-25% of the total amount of paclitaxel loaded into the stent is delivered in the first day, 95% of the loaded paclitaxel delivered by day 20 to 45.

15 49. The stent of Claim 40, wherein the paclitaxel is loaded for delivery after day one at a rate of about 0.25 micrograms to about 2.5 microgram per day for a minimum of 21 days for a stent with dimensions 3.0 mm in expanded diameter by 17 mm in length, and delivering other amounts from stents of other dimensions based on their respective relative proportions.

20 50. The stent of Claim 40, wherein the paclitaxel is affixed to the stent such that more than 80% of the paclitaxel loaded on the stent is delivered in no longer than 180 days.